REMARKS

Claims 3 and 11, as amended, appear in this application for the Examiner's review and consideration. Claims 1, 2, and 4-6 were cancelled without prejudice. Applicants reserve the right to pursue the subject matter of claims 1, 2, and 4-6 in a continuation, divisional, or continuation-in-part application. Claims 7-10 were withdrawn by the examiner as directed to non-elected subject matter.

Claim 11 has been amended for clarity and to include the compound of Formula I. This amendment is supported, for example, on page 6, lines 16 to 24 and page 8, lines 3 to 5 of the application as filed.

Claim 11 stands rejected under 35 U.S.C. § 101 for the reasons set forth on page 2 of the Office Action. Applicants respectfully traverse.

In order to satisfy the utility requirement of 35 U.S.C. § 101, the disclosures of an application must "establish a specific and substantial utility for the claimed invention." *See In re Fischer*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). To meet the "specific" utility requirement, an application must discloses a use "which is not so vague as to be meaningless." *See id.* In order to satisfy the "substantial" utility requirement, the disclosure "must show that the claimed invention has a significant and presently available benefit to the public." *See id.*

Claim 11 as amended renders moot the rejection. Now claim 11 recites: "a method of determining the presence and amount of an impurity in azithromycin comprising an azithromycin degradation product of claim 3 wherein the determination is performed with a reference standard having the degradation product of claim 3; and quantifying the amount of the azithromycin degradation product in a sample of azithromycin using the reference standard." Thus, the compound of claim 3 is described as being useful in a manner "not so vague as to be meaningless." Therefore, the rejection cannot stand and should be withdrawn.

Claim 11 stands rejected under 35 U.S.C. § 112, first paragraph, as allegedly not complying with the written description requirement for the reasons set forth on page 3 of the Office Action. Applicants respectfully traverse.

In a form paragraph, the Office sets forth its basis for this rejection on page 3: "The claim(s) contains subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Yet the facts within the specification clearly

contradict this statement. Applicant points out the published application at paragraph [0013] were applicants clearly set forth the description of an embodiment of the invention: "Another embodiment of the invention encompasses methods to **analyze** azithromycin purity comprising **assaying** azithromycin to **determine the presence and an amount**, if any, of azithromycin degradation products." Specification at p. 4, ll. 9-11 (emphasis added).

But this is not the only section of the application that describes this embodiment of the invention: "The invention encompasses analytical methods to determine the purity and/or the degradation stability of azithromycin comprising assaying an amount of azithromycin; determining the presence of degradation products; identifying the degradation products, and quantifying the amount of degradation products." Specification p. 6, ll. 17-20, ¶ [0032] of the publication.

Accordingly, the rejection of claim 11 under 35 U.S.C. § 112, first paragraph as not meeting the description requirement cannot stand and should be withdrawn.

Claims 1-4 stand rejected under 35 U.S.C. § 102(b) as purportedly anticipated by U.S. patent No. 4,474,768 to Bright *et al.* ("the '768 patent") for the reasons set forth at pages 3 and 4 of the Office Action. Applicants respectfully traverse.

It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert denied*, 480 U.S. 947 (1987). To anticipate a claim, a single reference must disclose the claimed invention with sufficient clarity to prove its existence in the prior art, and must disclose every element of the challenged claim. *Motorola Inc. v. Interdigital Technology Corp.*, 43 U.S.P.Q.2d 1481, 1490 (Fed. Cir. 1997); *PPG Industries Inc. v. Guardian Industries Corp.*, 37 U.S.P.Q.2d 1618, 1624 (Fed. Cir. 1996). Absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.*, 231 U.S.P.Q 160 (Fed. Cir. 1986). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). An anticipatory reference must also enable one of ordinary skill in the art as to the claimed subject matter.

Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will be deemed to anticipate a subsequent claim if the missing element "is necessarily present in the thing described in the reference." *Cont'l Can Co. v.*

Monsanto Co., 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). "Inherent anticipation requires that the missing descriptive material is necessarily present, not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295, 63 U.S.P.Q.2d 1597 (Fed. Cir. 2002).

The Office merely proposes that because the '768 patent discloses a pharmaceutical composition comprising azithromycin, that the natural consequence is that it also contains the degradation products. The Office proposes "the claimed compounds are degradation products of a known compound azithromycin disclosed by Bright." See Office Action p. 4. Yet, it is not the mere existence of azithromycin that causes these degradations products, but the storage conditions and time influence the degradation, none of which are discussed by the '768 patent. In fact, the '768 patent is silent as to the manner, method, or conditions in which azithromycin is stored.

Azithromycin may be stored in a variety of conditions that will determine whether or not degradation occurs and if so, what degradation products occur. All these factors are ignored by the Office Action. Without any guarantee, the Office Action proposes that the '768 patent azithromycin undergoes degradation. Yet, there is no way to be certain that the material will be present in the '768 patent. Even if one were to argue that degradation products would potentially form with the passage of time, it may depend on the type of storage packaging used and period of time stored. Packaging methods such as those discussed in U.S. Patent No. 3,331,495 to Leckzik *et al.*, and U.S. Publication Nos. 2004/101142 and 2005/021453 demonstrate that there are a number of ways to store azithromycin and the presence of degradation products may depend on these storage methods and storage periods. Because there is no way to know the method that the '768 patent used to store azithromycin as well as how long, one cannot be certain that the degradation products were present in the material.

Further, the '768 cannot anticipate the claims because it does not enable the skilled artisan to obtain the recited compounds and it fails to establish that such compounds could possibly be present within the prior art. The standard for inherency is that the missing descriptive material is necessarily present, not merely probably or possibly present. Here, the Office merely suggests the possibility that such compounds are present, and does not set forth any concrete scientific principle in support of its argument. In its speculation, the Office states "[s]ince azithromycin is subject to degradation that **may occur** during manufacture

and/or storage ... said degradation products are inherently present in the azithromycin composition disclosed by Bright." Office Action p. 4 (emphasis added). Applicants emphasize the phrase "may occur" to demonstrate that the rejection relies upon speculation and probability that compounds may be present. No certainty or scientific principle supports the Office's contention, here the Office is merely guessing as to the presence of the compounds.

Accordingly, the rejection of claims 3 and 11 under 35 U.S.C. § 102(b) as anticipated by '768 patent cannot stand and should be withdrawn.

Claims 3 and 11 stand rejected under 35 U.S.C. § 103(a) as purportedly rendered obvious over the '768 patent for the reasons set forth on pages 3 and 4 of the Office Action. Applicants respectfully traverse.

The consistent criterion for determination of obviousness is whether the prior art would have suggest to one of ordinary skill in the art that claimed subject matter should be carried out and would have a reasonable likelihood of success. *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). As the Examiner is well aware, in order to form a proper basis for a rejection under 35 U.S.C. § 103, the prior art must provide some suggestion, either explicit or implicit, of the combination that allegedly renders a claimed invention obvious. *M.P.E.P.*, § 2142 (June 1998), *see also, Panduit Corp. v. Denisson Manufacturing Co.*, 1 U.S.P.Q.2d 1593, 1597 (Fed. Cir. 1987). The Examiner can satisfy the burden of showing obviousness of the combination only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Sang Su Lee*, 277 F.3d 1338, 1343, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002); citing *In re Fritch*, 972 F.2d 1260, 1265, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The need for specificity is paramount, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected the components for combination in the manner claimed. *Id.* The Examiner's conclusory statements do not adequately address the issue of motivation to combine; the factual question of motivation is material to patentability, and can not be resolved on subjective belief and unknown authority. *Id.*

Applicants maintain their earlier arguments, which are incorporated herein by reference, and add the following. The Office ignores the statute for obviousness, which

applicants quote in part: "Patentability shall **not be negatived** by the manner in which the invention was made." 35 U.S.C. § 103(a) (emphasis added). In fact, the Office relies upon Applicant's disclosure to achieve the recited claims. Citing from the application, the Office maintains its obviousness rejection. No reasoning, no scientific explanation, and no certainty are presented in the Office's argument. It appears that the Office maintains its rejection based upon manner in which the invention was made. This is clearly contrary to the explicit language of the statute.

Rather than showing how the skilled artisan achieves the recited claims in view of the '768 patent, the Office merely makes the conclusory statement of obviousness without any supporting details. As discussed previously by applicants, the Office is reminded that conclusory statements do not adequately address the issue of motivation to combine; the factual question of motivation is material to patentability, and can not be resolved on subjective belief and unknown authority. The obviousness analysis lacks the basic factual inquiries as set forth by the Supreme Court in *Graham v. John Deere*, 383 U.S. 1 (1966), MPEP 2141 (8th Ed. 2001, last revision August 2006).

In fact, the Office cannot establish the rejection, because the '768 patent does not disclose or suggest either explicitly or implicitly the recited claims. There is simply no suggestion that the recited compounds are present in the '768 patent and there is no instruction as to how the skilled artisan would obtain them. Further, the skilled artisan lacks any reasonable expectation of success of obtaining the recited compounds, because the reference is unaware of their existence. Given this gross lack of information, the skilled artisan could not achieve the recited claims after reading the '768 patent.

Applicants include by reference all arguments presented in the amendment under 37 C.F.R. § 1.116 filed on June 19, 2007. Some additional claims were cancelled, however, the prior arguments presented in response to the § 102 and § 103 rejections are equally applicable to claims 3 and 11.

Accordingly, the rejection of claims 3 and 11 under 35 U.S.C. § 103(a) as rendered obvious by the '768 patent cannot stand and should be withdrawn. Accordingly, it is believed that claims 3 and 11 are now in condition for allowance, early notice of which would be appreciated.

If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 11-0600.

Respectfully submitted,

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